UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

In re: Nexium (Esomeprazole Magnesium) Antitrust Litigation This Document Relates to: All Actions	MDL No. 2409 Civil Action No. 1:12-md-02409-WGY

ASTRAZENECA AND RANBAXY DEFENDANTS' STATEMENT OF UNDISPUTED FACTS RELATING TO THEIR MOTION FOR SUMMARY JUDGMENT ON ALL CLAIMS ARISING FROM ASTRAZENECA'S SETTLEMENT WITH RANBAXY

Pursuant to Local Rule 56.1, AstraZeneca and Ranbaxy[1] respectfully submit this statement of material facts of record as to which there is no genuine issue to be tried.

1. AstraZeneca instituted patent litigation against Ranbaxy in 2005 in the U.S. District Court for the District of New Jersey asserting that Ranbaxy's proposed generic product infringed six patents, including one that expires in 2019. *See* Ex. 18 (Complaint, *AstraZeneca AB, et al. v. Ranbaxy Pharms., Inc., et al.*, 3:05-cv-5553-JAP-TJB (D.N.J. Nov. 21, 2005) [Dkt. No. 1]).[2]

2. In April 2008, shortly after discovery ended, AstraZeneca and Ranbaxy agreed to a settlement in which Ranbaxy received a license to market its generic Nexium product on or before May 27, 2014, more than five years before certain of the patents AstraZeneca had asserted against Ranbaxy expired. Ex. 1 (AstraZeneca-Ranbaxy Nexium Settlement Agreement) ¶¶ 5.1-5.2.

[1] This Statement of Undisputed Facts is filed on behalf of Defendants AstraZeneca LP, AstraZeneca AB and Atkiebolaget Hässle (collectively, "AstraZeneca") and Ranbaxy Pharmaceuticals, Inc., Ranbaxy Inc., and Ranbaxy Laboratories, Ltd. (collectively, "Ranbaxy").

[2] All exhibits referenced herein are exhibits to the Declaration of James H. Weingarten, Esq. in Support of Motions for Summary Judgment.

3. The license AstraZeneca granted Ranbaxy was exclusive during Ranbaxy's first-filer (180-day) statutory generic exclusivity period, with certain exceptions. Ex. 1 ¶ 5.1. The license permitted AstraZeneca to launch an authorized generic (or authorize a third party to do so) during the 180-day statutory exclusivity period if another third party launched a generic Nexium product prior to May 27, 2014 without a license. *Id.*

4. On the same day as the settlement, AstraZeneca and Ranbaxy also signed a series of business agreements. Ex. 37 (Plendil Distribution Agreement); Ex. 38 (Prilosec Distribution Agreement); Ex. 40 (Bailment Agreement); Ex. 41 (Supply Agreement); Ex. 42 (Tolling Agreement).

5. Two of the agreements between AstraZeneca and Ranbaxy were distribution agreements in which Ranbaxy agreed to distribute authorized generic versions of two drugs manufactured by AstraZeneca (Plendil and the 40 mg dosage of Prilosec). Exs. 37, 38.

6. In both of the distribution agreements, Ranbaxy agreed to pay AstraZeneca for drugs that AstraZeneca supplied. Ranbaxy agreed to pay AstraZeneca both a "Base Purchase Price" for the product manufactured by AstraZeneca, and a "Deferred Purchase Price" that represented a share of the profits that Ranbaxy realized from the final sale of the authorized generic product. *See* Ex. 37 ¶ 3.1 ("Distributor shall pay AstraZeneca the Base Purchase Price on the terms set forth in Section 3.3 and the Deferred Purchase Price on the terms set forth in Section 3.4"); Ex. 38 ¶ 3.1 (same). The Deferred Purchase Price Ranbaxy paid to AstraZeneca under both agreements consisted of 80% of Ranbaxy's net profit, as defined in the agreement. Ex. 37 ¶ 3.4.1; Ex. 38 ¶ 3.4.1.

7. Ranbaxy paid AstraZeneca a total of $72 million under the distribution agreements. *See* Ex. 39 (Excerpts from Expert Report of Gregory K. Bell, Ph.D.) ¶¶ 129, 132 & Exs. L, M.

8. Plaintiffs have no evidence that either the Base Purchase Price or the Deferred Purchase Price Ranbaxy paid AstraZeneca under these agreements was unreasonably low or did not represent fair market value. To the contrary, Plaintiffs' expert Thomas McGuire relies on the distribution agreements in his report, without making any claim that the terms of the agreements were commercially unreasonable. Ex. 52 (Excerpts from Expert Report of Richard G. Frank and Thomas G. McGuire) ¶ 192.[3]

9. Plaintiffs have offered an expert who attempts to quantify the profits that Ranbaxy earned for the services that it performed in distributing authorized generic versions of Plendil and Prilosec. *See* Ex. 52 ¶¶ 171–72. However, none of Plaintiffs' experts offers the opinion that the authorized generic distribution agreements did not reflect an exchange of fair value between the parties.

10. Retailer Plaintiffs' expert Keith Leffler, Ph.D., testified in his deposition that he is not offering any opinion about the economic value of the Prilosec or Plendil distribution agreements. Ex. 82 (Excerpts from Leffler Dep.) at 80–81. Class Plaintiffs' expert Thomas McGuire admitted that he had never seen an authorized generic distribution agreement prior to this case. Ex. 53 (Excerpts from McGuire Dep.) at 175. His report does not address whether the authorized generic distribution agreements reflect an exchange of fair value between the parties. Ex. 52 ¶¶ 171–172. Similarly, Class Plaintiffs' expert Shashank Upadhye makes no attempt to address this issue in his report. Ex. 17 (Excerpts from Report of Shashank Upadhye) ¶¶ 218–23

[3] Professor Frank has been withdrawn as an expert for the Class Plaintiffs.

(addressing agreements without opining regarding fair market value). He admitted in his deposition that he has not performed any analysis of whether the agreements involve fair market value for legitimate services. Ex. 51 (Excerpts from Upadhye Dep.) at 261. Nor has he done any analysis of the parties' performance under these agreements. *Id.*

11. AstraZeneca entered into three other business agreements with Ranbaxy on April 14, 2008. In one of those agreements, a Bailment Agreement, AstraZeneca paid Ranbaxy a nominal fee of $1 for storage of AstraZeneca product in Ranbaxy's warehouses. Ex. 40 ¶ 3. In the second agreement, an API Supply Agreement, Ranbaxy agreed to supply 50% of AstraZeneca's esomeprazole magnesium (*i.e.*, the active ingredient for Nexium) requirements for the U.S. market. Ex. 41. In the third agreement, the Tolling Agreement, Ranbaxy agreed to supply 33% of AstraZeneca's finished Nexium capsule requirements for the U.S. market. Ex. 42.

12. Plaintiffs have no evidence that the prices Ranbaxy charged under the API Supply Agreement and the Tolling Agreement were not fair market prices or that Ranbaxy did not perform real services under those agreements.

13. Class Plaintiffs' expert Thomas McGuire admitted that he does not know whether the business agreements between AstraZeneca and Ranbaxy were for fair market value. Ex. 53 at 175–77, 180, 183–85. He did nothing to evaluate whether AstraZeneca paid a fair price to Ranbaxy under the Tolling Agreement, *id.* at 185, and has no experience with such agreements, *id.* at 186.

14. Similarly, Class Plaintiffs' expert Shashank Upadhye admitted in his deposition that he has not performed any analysis of whether AstraZeneca is paying fair market value for legitimate services under its business agreements with Ranbaxy. Ex. 51 at 261 (Q: "Have you

performed any analysis to determine whether AstraZeneca is paying above, below, or at fair market value for the products being supplied under these so-called 'parallel agreements'?" A: I personally have not done any of that analysis."). Nor has he done any analysis of the parties' performance under these agreements. *Id.*

15. Retailer Plaintiffs' expert Keith Leffler opines that Ranbaxy benefitted from the API Supply Agreement and Tolling Agreement and received payments under those agreements. Ex. 81 (Excerpts from Leffler Rebuttal Report) ¶¶ 14, 18. But Dr. Leffler did not perform any analysis of whether the prices contained in the agreements between AstraZeneca and Ranbaxy reflect fair market value for the services rendered by Ranbaxy. *See id.*

16. With respect to the API Supply Agreement, Dr. Leffler admitted in his deposition that he is not an expert in esomeprazole API pricing. Ex. 82 at 109. He merely observes that, in 2004, AstraZeneca obtained quotes from other potential suppliers and decided not to outsource its Nexium API. Ex. 81 ¶ 15. That observation does not address whether the terms of the agreement Ranbaxy and AstraZeneca entered into in 2008—four years later—were for fair market value. Indeed, Dr. Leffler admitted in his deposition that he has no knowledge of why AstraZeneca did not accept the proposals made by other suppliers in 2004 or of AstraZeneca's evaluation of the suppliers' reliability or the quality of their supply. Ex. 82 at 111–12.

17. Dr. Leffler also asserts that the API Supply Agreement "was quite profitable to Ranbaxy." Ex. 81 ¶ 15. But he does not address whether the agreement involved fair value for the services rendered. Dr. Leffler does not claim to have any knowledge of the appropriate profit margins in such agreements or whether Ranbaxy's profit margin exceeded the profits margins in comparable agreements. *See id.*

18. With respect to the Tolling Agreement, Dr. Leffler asserts that Ranbaxy profited from the agreement, and that this suggests that "AstraZeneca could have received lower prices, much closer to the Ranbaxy cost, had it contracted for competitive supply of the capsules." Ex. 81 ¶ 17. But Dr. Leffler has not performed any analysis of whether the prices charged to AstraZeneca by Ranbaxy under the agreement were for fair market value. He admitted in his deposition that he did not perform any analysis of a competitive market price for the capsules or of Ranbaxy's profit margins in other capsule supply agreements. Ex. 82 at 116–17. He does not identify any other comparable agreements or attempt to determine the appropriate profit margin in a capsule supply agreement. *See* Ex. 81 ¶ 17.

19. The Ranbaxy settlement was entered into at a time when authorized generics were considered potentially anticompetitive and the FTC was in the process of studying "the short and long term effects on competition of the practice of 'authorized' generics" at the request of Senators Grassley, Leahy, and Rockefeller. Ex. 44 (Letter from Sens. Charles Grassley, Patrick J. Leahy, and John D. Rockefeller IV to Deborah Platt Majoras, Chairman, Fed. Trade Comm'n (May 9, 2005)).

20. FTC Commissioner Leibowitz stated on September 20, 2006 that FTC staff were in the process of conducting a study of authorized generics and "[q]uite rightly, the Commission will wait for the results of the study before developing a position or taking any action." Ex. 45 (How Settlements Make Strange Bedfellows: Or How the Federal Trade Commission has Managed to Unite the Entire Pharmaceutical Industry (but only in Opposition to the FTC's Position on Exclusion Payment Settlements)) at 5.

21. The FTC did not conclude its study until 2011. Ex. 46 (FTC press release, Aug. 31, 2011). It issued an interim report in 2009, after AstraZeneca's settlement with Ranbaxy. Ex. 47 (FTC press release, June 24, 2009).[4]

22. Prior to the FTC's interim report in 2009, Congressional legislators were calling for an outright ban of authorized generics during the 180-day generic exclusivity period. They did so because of a stated concern that authorized generics reduced the incentives of generic firms to aggressively pursue generic applications. Ex. 48 (Letter from Hon. Henry A. Waxman, U.S. House of Representatives, to Deborah Platt Majoras, Chairman, Fed. Trade Comm'n (Sept. 13, 2005)); *see also* Ex. 45.

23. Congressman Henry Waxman (one of the sponsors of the Hatch-Waxman Act) asserted in 2005 that authorized generics were an "unfair practice" and that the 180-day exclusivity period was intended to give the first-filing generic "six months of marketing without any other generic competition." Ex. 49 (Speech: Generic Pharmaceutical Association's First Annual Policy Conference (Sept. 20, 2005) (statement of Rep. Waxman), *available at* http://waxman.house.gov/speech-generic-pharmaceutical-associations-first-annual-policy-conference).

24. In 2006, Senator Rockefeller asserted that "[a]uthorized generics are a sham" and that "[t]his practice undermines congressional intent and harms consumers by preventing generic competition and eliminating billions of dollars in prescription drug savings over the long-term."

[4] Defendants cite these documents solely for the dates of the FTC's reports regarding authorized generics. As set forth in the accompanying memorandum of law, the information contained in the FTC's 2009 interim report and final 2011 report on authorized generics was not available to AstraZeneca and Ranbaxy at the time of the 2008 settlement. The settlement must be considered in the context of the surrounding circumstances at the time of the settlement, not events that post-dated it.

Ex. 50 (Press Release, July 20, 2006). Senators Schumer and Leahy similarly condemned the use of authorized generics during this time frame. *Id.*

25. In 2006, Congressman Waxman and Senators Rockefeller, Schumer and Leahy sponsored bills in the House and Senate that would have banned altogether the use of authorized generics. Ex. 54 (H.R. 5993, 109th Cong. (2006)); Ex. 55 (S. 3695, 109th Cong. (2006)).

26. In 2007, Senators Rockefeller, Schumer, Kohl, and Leahy and several members of the House of Representatives again sponsored bills to ban the use of authorized generics. Ex. 56 (H.R. 806, 110th Cong. (2007)); Ex. 57 (S. 438, 110th Cong. (2007)).

27. On January 30, 2007, Senator Rockefeller reiterated his view that "authorized generics are a sham." Ex. 58 (Congressional Record (Jan. 30, 2007) S1352).

28. The FTC also made public pronouncements prior to the 2008 AstraZeneca-Ranbaxy settlement raising concerns about authorized generics. In 2005, FTC Commissioner (later Chairman) Jon Leibowitz stated: "the long-term implications of [innovators' use of authorized generics] are potentially troubling. The introduction of an authorized generic will likely diminish the incentives for generic firms to challenge patents and incur substantial development and litigation costs." Ex. 59 (Jon Leibowitz, *Health Care and the FTC: The Agency as Prosecutor and Policy Wonk*, speech, at 10 (May 12, 2005)). In 2006, Commissioner Leibowitz reiterated his concern that "the growing use of authorized generics may diminish a generic's incentives to fight." Ex. 60 (Jon Leibowitz, *Exclusion Payments to Settle Pharmaceutical Patent Cases: They're B-a-a-a-ck*, speech, at 7 (Apr. 24, 2006)).

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I, James H. Weingarten, hereby certify that this document was served via email on counsel of record for all parties on December 10, 2013..

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